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09/380,695	03/29/2002	Dirk Gerrit Meuleman	0/97263 US	5130

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EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/380,695
Filing Date: March 29, 2002
Appellant(s): MEULEMAN ET AL.

David H. Vickrey
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 7, 2005 appealing from the Office action mailed December 14, 2004.

(1) (1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

The rejections under 35 U.S.C. 103(a) over Haenggi et al. are herein withdrawn.

The rejections under 35 U.S.C. 103(a) over Haenggi et al. in view of Berglund are maintained and to be reviewed.

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(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Haenggi et al. 'Postmenopausal hormone replacement therapy with tibolone decrease serum lipoprotein (a),' Eur. J. Clin. Chem. Clin. Biochem. 1993, Vol. 51, pages 645-650.

Berglund 'Diet and drug therapy for lipoprotein (a),' Current opinion on lipidology, 1995, vol. 6, No. 1, pages 48-56.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haenggi et al. (of record), in view of Berglund.

Haenggi et al. teach a method of decreasing lipoprotein (a) by administering 7alpha-methyl-17alpha-ethynyl-17beta-hydroxy-5(10)-estren-3-one (Tibolone), to a human subject, see the entire document, the abstract in particular. Haenggi further teaches that Lp(a) has been shown to be a strong independent risk factor for coronary disease, see the abstract. Haenggi also teach a method of treating postmenopausal women with Tibolone in an effective amounts herein defined. (page 646, Patients and Methods, and page 6, lines 25-30 herein in the specification).

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Haenggi et al. does not teach expressly the employment of Tibolone in a method of inhibiting atherosclerosis.

However, Berglund teaches that Lp(a) has been implicated with an increased risk of atherosclerosis, see the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Tibolone in a method of inhibiting atherosclerosis, e.g., by administering to a subject being suffering from atherosclerosis Tibolone.

A person of ordinary skill in the art would have been motivated employ Tibolone in a method of inhibiting progress of atherosclerosis because Lp(a) has been implicated an increased risk of atherosclerosis, and lowering the level of lipoprotein (a) would have reasonably expected to inhibit the progress of atherosclerosis.

Further, it would have been obvious to one of ordinary skill in the art, at the time the claimed invention was made, to use the method of Haenggi et al. to postmenopausal women suffering from atherosclerosis since Haenggi et al. show tibolone would provide some benefit for inhibiting the progress of atherosclerosis, as discussed above.

(10) Response to Argument

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

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applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It is noted that appellants do not dispute the fact that “a substantial portion of the population of postmenopausal women are suffering atherosclerosis,” but argue that Haenggi et al. disclose that Tibolone also decrease the HDL-cholesterol. The arguments are improper. Particularly, the cited prior arts established that Lp(a) is closely associated with atherosclerosis, therefore, decrease of Lp(a) would have been reasonably expected to suppress, or inhibit the development of atherosclerosis. Applicants argue that Tibolone decrease HDL-cholesterol, however, fails to establish the relationship of the decrease of HDL-cholesterol and atherosclerosis. Applicants fails to establish a prima facie case that decrease of HDL-cholesterol would have discourage one of ordinary skill in the art from using Tibolone for inhibiting atherosclerosis. Note, Haenggi et al. merely teaches that lowering lipoprotein (a) would counter balance the adverse effect of tibolone on other lipoprotein risk factors. There is no teaching as to the relation of those factors and atherosclerosis. Further, even if it is known that decrease of HDL-cholesterol is associated with atherosclerosis, there is no sufficient evidence to show that the decrease of HDL-cholesterol would out weight the benefit of lowing Lp(a), particularly, in view the fact that Lp(a) has been shown to be a strong independent risk factor for coronary heart disease.

Appellants contend that the instant claims are based on the discovery of unexpected benefit resided in the claims. The arguments are not persuasive. The examiner fails to see the alleged “unexpected” results commensurate in scope with the claimed invention. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant’s

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burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). The claims are directed to mammal in general, and in human in particular. The data is based on rabbit, which, applicants admitted, is different from other mammal, such as human (Lp(a) not present, page 6 of the response submitted December 30, 2003). There is no reasonable expectation that such unexpected result would be extrapolated to other mammal. Therefore, the unexpected results are not commensurate with the scope herein claimed. Further, in view the fact that substantial portion of postmenopausal women have atherosclerosis, treating menopausal women suffering from atherosclerosis would have been obvious over Heanggi et al. in view of Berglund.

(11) Related Proceeding(s) Appendix


No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

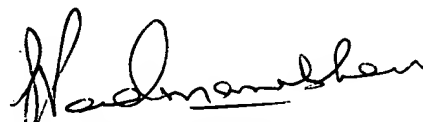
Respectfully submitted,


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